

REMARKS:

In response to the Office Action mailed November 29, 2002, claims 6 and 13 have been amended, and new claims 38-49 have been added, in order to more particularly claim the subject matter of the present application.

In the Office Action, claim 13 was objected to for lack of clarity, and claim 6 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In addition, claims 1, 2, 5-8, and 16 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,849,497 ("the Steinman reference"). Finally, claims 3, 4, and 9-12 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Steinman reference in view of U.S. Patent No. 5,863,717 ("the Lancaster et al. reference"), and claims 13 and 15 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Steinman reference in view of U.S. Patent No. 6,045,993 ("the Mahoney et al. reference"). Because none of the cited references, alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

First, Applicants appreciate the Examiner's indication that claim 14 would be allowable if rewritten in independent form, including all limitations of the base claim and any intervening claims. Claim 14 will be dealt with when the final status of the present application is determined.

Turning to the claim objections, claim 13 has been amended to refer separately to each primer by its SEQ. ID. NO., as suggested by the Examiner. In addition, with respect to the § 112 rejections, claim 6 has been amended to recite that "said at least one probe further comprises a nucleotide having a different sequence from PNA." Therefore, the claim objections and § 112 rejections should be withdrawn.

With respect to the § 102(b) rejections, the Steinman reference discloses a method for identifying different organisms, such as bacteria and viruses, by inhibiting amplification of specific targets when subjected to PCR technology. Col. 5, lines 13-16. Although the Steinman reference mentions that sequence-dependent blocking using PNA is known, the Steinman reference expressly teaches against using PNA, and instead discloses an alternative method that doesn't use PNA. Col. 2, lines 44-65.

Turning to the present claims, claim 1 recites a method for detecting the presence of at least one selected strain of an organism in a sample that may include nucleic acid from at least one selected strain of an organism and nucleic acid from at least one non-selected strain of the organism. The Steinman reference fails to teach, or suggest detecting the presence of at least one selected strain of an organism in a sample that may include nucleic acid from a selected strain of an organism and nucleic acid from a non-selected strain of the organism, as claimed. Instead, the Steinman reference merely discloses a method for identifying different organisms that may be present together in a sample. Therefore, claim 1 and its dependent claims are neither anticipated nor otherwise obvious in light of the Steinman reference.

Turning to claim 38, a method is recited for detecting the presence of at least one selected strain of human papilloma virus (HPV) in a sample that may include nucleic acid from a selected strain of HPV and nucleic acid from a non-selected strain of HPV. The sample is exposed to at least one probe that is sufficiently complementary to a portion of the nucleic acid from at least one non-selected strain to block full length amplification of the nucleic acid from at least one non-selected

strain between a plurality of primers, the at least one probe including a nucleic acid analog comprising PNA.

First, the Steinman reference does not disclose, teach, or suggest detecting the presence of at least one selected strain of human papilloma virus (HPV) in a sample that may include nucleic acid from a selected strain of HPV and nucleic acid from a non-selected strain of HPV, as claimed. As explained above, the Steinman reference fails to teach or suggest detecting a selected strain of an organism in the presence of a non-selected strain of the same organism. In addition, the Steinman reference teaches nothing about HPV, but, at most, discloses identifying different bacteria or viruses. Finally, the Steinman reference does not disclose, teach, or suggest exposing a sample to a probe including PNA, and, in fact, expressly teaches against using a probe including PNA. Accordingly, claim 38 and its dependent claims are also neither anticipated nor otherwise obvious in light of the Steinman reference.

With respect to the other cited references, although the Mahoney et al. reference discloses genotyping HPV, the Mahoney et al. reference may not be properly combined with the Steinman reference to render the present claims obvious. First, the Mahoney et al. reference discloses using primers to amplify HPV to produce L1 amplicons, and then using a sequencing primer and a chain termination sequencing method to determine the nucleic acid sequence of part of the L1 amplicons. Col. 3, lines 5-13. Thus, the Mahoney et al. reference discloses a method that is completely incompatible with the method disclosed in the Steinman reference. Therefore, there is no motivation to combine these references, other than improper hindsight based upon the disclosure of the present application.

Similarly, the Lancaster et al. reference may not be properly combined with the Steinman reference. The Lancaster et al. reference merely discloses universal primers that are used in polymerase chain reaction to amplify any source of HPV DNA. Col. 6, lines 19-28. Type-specific probes may then be used on fragments of the products to identify HPV strains. Col. 4, line 57 through col. 5, line 2.

Thus, neither of the Mahoney et al. nor the Lancaster et al. references discloses, teaches, or suggests exposing a sample to at least one probe that is sufficiently complementary to a portion of a nucleic acid from at least one non-selected strain to block full length amplification, and amplifying the nucleic acid from at least one selected strain, as claimed. In contrast, both reference disclose amplifying all strains of HPV present in a sample, and then uses a subsequent procedure to identify the strains. Accordingly, the present claims are not obvious in light of the cited references, either alone or in combination with one another.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,
BINGHAM McCUTCHEN LLP

Dated: March 27, 2003

By: 

William A. English
Reg. No. 42,515
Attorneys for Applicants

Three Embarcadero Center, Suite 1800
San Francisco, California 94111
Telephone: (213) 680-6831
Facsimile: (213) 680-6499